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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,797	09/13/2001	John Walker	017227-0175	9643

22428 7590 04/15/2003

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

857,797

Applicant(s)

WALKER

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 111; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-19 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-19 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1644

The claims pending and under examination are 1-19.

Amendment of 9/13/01 has been entered.

Claims 8-12, 16 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 8, 10-12 and 16 applicant recites "immunostimulating complex", while in claims 2 and 6-7 applicant recites "immunostimulatory complex". Consistency in terminology is required.

In claims 10-12 and 16 recitation of "immunostimulatory complex" is unclear because its relationship to the saponin component of base claim 1 has not been defined.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Art Unit: 1644

In the present instance, claim 8 recites the broad recitation "in the range of 50 to 300", and the claim also recites "in the range of 100-140" which is the narrower statement of the range/limitation.

Claim 19 provides for the use of an adjuvant, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1644

Claims 1, 3-5, 13-14 and 17-19 are rejected under 35 U.S.C. 102(b) as being entirely anticipated by James et al. (WO 88/07547).

James et al. teach immunization of animals against a peptide-carrier conjugate. The adjuvant comprises DEAE dextran and saponin as active components, and PBS, as a diluent. See Example II (pages 13-17, especially at page 14). Claims 1, 3-5, 13 and 17-19 are thus anticipated.

James et al. teach that the peptide component can include LHRH or a part thereof (para. Spanning pp. 6-7). Thus claim 14 is anticipated.

Claims 1, 3-5 and 13-14 and 17-19 are rejected under 35 U.S.C. 102(b) as being entirely anticipated by Moss et al. (WO 91/04052).

Moss et al. teach immunization of animals with peptide-carrier conjugates. They use an adjuvant of saponin and DEAE dextran and a carrier or diluent. They exemplify conjugates having peptide component derived from GnRH (same as LHRH).

Claims 1, 3-5, 13 and 17-19 are rejected under 35 U.S.C. 102(a) as being entirely anticipated by Edgar et al. (WO 99/27959).

Art Unit: 1644

Edgar et al. teach immunization with peptide-carrier conjugates they use an adjuvant comprising DEAE dextran and saponin. See Examples. The examples show these components in a diluent such as PBS or ^tserile water._Λ

Citation of Edgar et al. is proper because applicant's priority document, PP8073, cannot support claims that are any broader than for the case in which the saponin component is in an ISCOM. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made. Claims 1 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al. or Moss et al., either in view of McNamara (WO 99/02180).

The primary references have been cited further above against claims 1 and 13-14. McNamara teaches the further feature of providing a LHRH peptide conjugated to diphtheria toxoid. He teaches that such LHRH conjugates are more immunogenic and more effective in fertility control than are previously provided conjugates of LHRH and carrier proteins. See page 9, lines 1-6.

Art Unit: 1644

One would hence have been motivated to use a LHRH-diphtheria toxoid conjugate, as taught by James et al., in lieu of the LHRH-protein conjugates of James et al. or Moss et al.

Claims 1-2, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al. or Moss et al., either in view of Mackenzie et al. (4,981,684).

James et al. and Moss et al. have been cited further supra against claim 1. Mackenzie et al. teach the further feature of providing a saponin adjuvant component in an Iscom. Examples show Iscoms comprised of Quil A, cholesterol and a phospholipid. Iscoms are taught as providing for an immunogenic effect with less adverse reactions. See col. 1, lines 26-30. In order to gain the advantage of reducing adverse reactions due to Quil A, it would have been obvious to incorporate the saponin component of James et al. or Moss et al. into an Iscom.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.


Art Unit: 1644

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

April 4, 2003


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ /644